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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/026,517	<b>Applicant(s)</b> ZHOU, PU	
	<b>Examiner</b> LAURA C. SCHELL	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,7-9,11,12 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,7,8 and 30-32 is/are allowed.
- 6) ☒ Claim(s) 9,11,12,29,33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Allowable Subject Matter***

The indicated allowability of claims 9, 11, 12, 29 and 33 is withdrawn in view of the newly discovered reference(s) to Flynn (US 5085649). Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 11, 12, 29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flynn (US Patent No. 5,085,649) in view of Bolduc et al. (US Patent NO. 6,622,367). Flynn discloses the device substantially as claimed including a medical catheter system (Fig. 1) comprising: a first steerable guide catheter having an entrance

orifice, an exit orifice, and a first wall surrounding a channel linking the entrance orifice and the exit orifice (Fig. 1; col. 5, lines 26-34 disclose that the tubing in Fig. 1 is used specifically for catheters which have entrance and exit orifices and a channel surrounded by a first wall as seen in Fig. 1), the first wall having a bendable curve memory portion (col. 5, lines 44-48 disclose that the catheters may be formed with flaring, which can be considered a bendable curve memory portion, as the applicant has not defined in the claim what a bendable curve memory portion is. Furthermore col. 5, lines 52-54 and 64-65 disclose that the tip of the catheter may be formed with a bend or a loop. As this is how the catheter is used, with the bend or the loop, the material in this portion somehow retains this bend or loop and therefore it can be said that this portion of the catheter has a curve memory portion, as there is no further structural claim limitation provided by Applicant.), wherein the bendable curve memory portion is bent into a predetermined shape and contains a plurality of flushing orifices (col. 5, lines 52-54 and 64-65 disclose that the catheter is bent into a predetermined shape and col. 6, lines 8-10 disclose that side holes are formed in the curved portion of the tubing) and wherein the first wall contains a first layer (Fig. 1, first layer is 2), a second layer (second layer is 4) and a third layer (third layer is 6), each layer having a different hardness (col. 3, lines 2-10 discloses that each layer has a different range of hardness. If one uses the uppermost limit in each range, for example the inner layer being 80, the middle layer being 100 and the outer layer being 85, then each layer does in fact have a different hardness. Furthermore, since the reference lists ranges of durometers that

can be used, it is possible that other combinations of different hardnesses are possible as well.).

Flynn, however, does not disclose a flushing line positioned about the first catheter. Bolduc, however, discloses a catheter system (Fig. 19) which has a guide catheter (500; col. 18, lines 41-45 disclose that catheter 500 may also be catheter 400 in Fig. 12, which is what the examiner is now interpreting to be the guide catheter) which has flushing orifices (Fig. 12, 408 and 410). The catheter system in Fig. 19 further discloses a flushing line positioned about the first catheter (the examiner is interpreting sheath 60 to be the flushing line, as col. 19, lines 27-31 disclose that 60 may be used to infuse fluids from the fluid system 715 which would then flow around catheter 500/400 and therefore be in fluid communication with the flushing orifices). Bolduc further discloses that the catheter 400/500 may be manufactured in any suitable conventional manner such as that described in columns 22-25. In particular, col. 24, lines 48-51 and 61-66 disclose that the catheter is made with multiple regions of varying hardness, to allow the catheter to have the hardness, strength and flexibility needed be a guide catheter and col. 24, lines 37-39 disclose that the catheter may be made with a shape memory alloy (curve memory portion). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Flynn's catheter to include a flushing line positioned about it, as taught by Bolduc, as Bolduc teaches a steerable guide catheter with varying regions of hardness for better control, a bendable curve memory portion and flushing orifices, and further teaches that it is known in the art to position a flushing line about this type of catheter.

In reference to claim 11, Flynn discloses that the first wall contains a reinforcing structure (col. 2, lines 47-64 disclose that the softer interior portion of the catheter may extend beyond the harder concentric shell in order to allow the distal portion of the catheter to be soft and pliable for navigating the venous system. This indicates that the first wall of the catheter, the portion that includes the concentric shell, has a reinforcing structure in order to allow the proximal portion of the catheter to be used to direct the distal portion of the catheter and prevent it from buckling) and the bendable curve memory portion comprises a curve memory material (as described in the paragraphs above, the material of the catheter is such that a permanent curve may be made to a portion of the catheter, and since Applicant has not further defined in the claim what a curve memory material is, Flynn's material reads on the claim).

In reference to claim 12, Flynn discloses that the inside surface of the first catheter includes a lubricious treatment (col. 4, lines 26-32 disclose that the catheter may be formed with lubricants).

In reference to claim 29, Flynn discloses that the plurality of flushing orifices extend through at least two of the layers (col. 5, lines 46 and col. 6, lines 8-10).

In reference to claim 33, Flynn discloses that the first layer, the second layer, and the third layer are concentric (Fig. 1 discloses that at least a portion of the catheter has all three layers disposed concentrically about each other), and the first layer is an inner layer (first layer is layer 2 which is the inner layer), the second layer is a middle layer (4) and the third layer is an outside layer (6), and the first layer is harder than the second layer (col. 2, lines 18-30; furthermore, the listed durometers for each layer are listed as

ranges that overlap so it is possible that one permutation of the hardness of the layers would allow the inner layer to be harder than the second layer).

### ***Allowable Subject Matter***

Claims 1, 3, 7, 8, 30-32 are allowed. The following is a statement of reasons for the indication of allowable subject matter: The amendment to independent claim 1 which necessitates the second catheter to have a bendable curve memory portion made from a cross-linking polymer activated by ultraviolet light, was not found.

### ***Response to Arguments***

Upon broadening the search in addition to updating the search for this application, the examiner found a new reference (Flynn, used in the rejection above) which required the allowability of claims 9, 11, 12, 29 and 33 be withdrawn.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767